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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,772	10/22/2003	Christopher M. Kim	CKIM 3.0-001 DIV	6954

530 7590 11/13/2007

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,772	KIM, CHRISTOPHER M.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 19-32* is/are pending in the application.

4a) Of the above claim(s) *26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/2007 has been entered.

2. Claims 11 and 19-32 are pending.

3. Newly submitted claims 26-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 26-31 are directed to a method of producing dried bee venom crystals and Claim 32 is directed to an extractor for collecting bee venom.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 11 and 19-25 are currently under examination as they read on a pharmaceutical compound comprising bee venom.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwaldt et al. (Reference CD on the IDS filed 10/22/2003, entire document).

Steigerwaldt et al. teaches a standardized bee venom preparation comprising bee venom administered by intradermal injection as a therapy for rheumatoid arthritis (In particular, page 1047, left column second to last paragraph to second to last paragraph in right column). Specifically, between .06 and 1.62 mg of bee venom was given in .1 ml (.1cc) of liquid carrier per injection for 8 injections to 50 patients (In particular, page 1047, right column).

Claim 11 is included in this rejection because injections of .06 mg, 1.62 mg and 4.8 mg (8 injections of .06mg) are within the range of "about .l mg to about 10 mg by weight of bee venom per mL of said liquid carrier."

Claims 11 and 19-25 are included in this rejection because standardized bee venom preparation produced by filtering the preparation adds no patentable weight since the been venom preparation of Steigerwaldt et al. is for in vivo use and is inherently sterilized, purified

and substantially free of bacteria, viruses and bacterial debris for pharmaceutical use. In addition, Applicant has claimed a standardized bee venom preparation **comprising** bee venom. The open language of the claim allows for the addition of other components, including the bacterial and viral impurities that applicant seeks to filter out. The intradermal injection of the standardized bee venom would appear to be compatible with physiological sterile condition, and not incompatible with pharmaceutical use.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced bee venom preparation for pharmaceutical *in vivo* use. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Further, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113. Therefore, the limitation of "said preparation being filtered through a filter" lends no patentable weight to the claims.

The prior art teachings anticipate the claimed invention.

Applicant's arguments filed on 11/02/2007 have been fully considered, but are not found persuasive.

Applicant argues that Steigerwaldt et al. does not teach that its bee venom preparation is substantially free of bacteria or viruses.

It is the Examiner's position, as discussed supra, that Steigerwaldt teaches a bee venom composition that is for in vivo use and inherently sterilized and substantially free of bacteria or viruses.

7. Claims 11 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Simics et al. (PTO -892 mailed on 01/04/2007, Reference U)

Simics et al. teaches a standardized bee venom preparation comprising bee venom administered by injection as a therapy (In particular, whole document). Specifically, Simics et al teaches injecting 1.0 mg of bee venom in 1 ml of liquid carrier that has been filtered by a micropore filter (filtered, substantially free of bacteria, viruses and bacterial debris) (In particular, page 108, first column).

Claim 11 is included in this rejection because injections of 1mg of bee venom in 1ml of liquid carrier is within the range of "about .1 mg to about 10 mg by weight of bee venom per mL of said liquid carrier."

Claims 11 and 19-25 are included in this rejection because the filtered standardized bee venom preparation of Simics et al. is inherently substantially free of bacteria, viruses and bacterial debris. In addition, Applicant has claimed a standardized bee venom preparation **comprising** bee venom. The open language of the claim allows for the addition of other components, including the bacterial and viral impurities that applicant seeks to filter out. The intradermal injection of the standardized bee venom would appear to be compatible with physiological sterile condition, and not incompatible with pharmaceutical use.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced bee venom preparation for pharmaceutical *in vivo* use. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority

to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Further, the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), MPEP 2113. Therefore, the limitation of "said preparation being filtered through a filter" lends no patentable weight to the claims.

The prior art teachings anticipate the claimed invention.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 8, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad
MAHER M. HADDAD
PRIMARY EXAMINER